



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/711,619	11/13/2000	Gurmukh S. Johal	35718/205458	7883

29122 7590 05/21/2003

ALSTON & BIRD LLP
PIONEER HI-BRED INTERNATIONAL, INC.
BANK OF AMERICA PLAZA
101 SOUTH TYRON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
----------	--------------

1638

DATE MAILED: 05/21/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No. 09/711,619	Applicant(s) JOHAL ET AL.	
	Examiner David H Kruse	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18,20-24 and 33-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18,20-24 and 33-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>17</u> . | 6) <input type="checkbox"/> Other: _____ |

STATUS OF THE APPLICATION

1. This Office action is in response to the Amendment and Remarks filed 4 March 2003.
2. The Information Disclosure Statement filed 4 March 2003 has been considered, a signed copy is attached hereto.
3. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments and/or arguments.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 22, line 23. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

6. Claims 1-18 and 20-24 remain rejected and claims 33-41 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 4 November 2002. Applicant's arguments filed 4 March 2003 have been fully considered but they are not persuasive.

Applicant argues that Applicant has provided exemplary sequences of the invention and have thus provided a structural definition of the sequences of the invention. Applicant also argues that Applicant has provided assays by which those of skill in the art can readily assess whether a nucleic acid molecule meeting the nucleotide sequence element of the claims also meets the functional limitation of the claims (page 9, 2nd paragraph of the Remarks). This argument is not found to be persuasive because the instant Application only describes a single species of the claimed genus of P-glycoproteins as directed to a nucleotide molecule that encodes the amino acid sequence of SEQ ID NO: 9, SEQ ID NOs 7 and 8 being two examples of said genus related as species and subspecies. The genus of nucleotide molecules of the instant claims have not been adequately described except by the function of the encoded protein and a method of isolating them. In *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), the court states that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. In the instant case, the application does not describe features, which constitute a substantial portion of the claimed genus. In addition, Applicant does not describe the claimed genus because the function of the exemplified nucleotide molecule, encoding a P-glycoprotein, does not clearly describe a genus of nucleotide molecules that control plant growth (see paragraph spanning pages 5-6). It was recognized in the art prior to Applicant's

invention that P-glycoproteins are a genus of integral membrane proteins that function as energy-dependent transporters and that their substrates belong to a wide array of various substances with different functions (see Dudler *et al* 1992, J. Biological Chemistry 267(9):5882-5888, especially page 5882).

Applicant argues that the description is sufficient to distinguish the claimed genus from other material and that a disclosure of many species within the claimed genus is not required (page 9, 3rd paragraph of the Remarks). This argument is not found to be persuasive for the reasons given above.

7. Claims 1-18 and 20-24 remain rejected and claims 33-41 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated nucleotide molecule encoding the amino acid sequence of SEQ ID NO: 9 and a method for modifying the height of a sorghum plant comprising transforming said sorghum plant with a construct comprising a nucleotide molecule having the nucleotide sequence of SEQ ID NO: 7 or 8 in either the sense or antisense configuration, does not reasonably provide enablement for any isolated nucleotide molecule that is 80-95% identical to SEQ ID NO: 7 and 8 encoding a P-glycoprotein that controls plant growth or to a method of modifying the growth of any organism or specifically a plant comprising transforming said organism with said nucleotide molecules encoding a P-glycoprotein that functions to control growth of an organism. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 4

November 2002, and has been modified to more clearly define the scope of enablement. Applicant's arguments filed 4 March 2003 have been fully considered but they are not persuasive.

Applicant argues that provided with the exemplary disclosed nucleotide sequence of SEQ ID NO: 7 and 8 those of ordinary skill in the art can readily determine the nucleic acid sequence of a nucleic acid molecule as well as the percent identity between any two sequences. Applicant argues that routine assays are known in the art that can be used by those of ordinary skill in the art to readily determine whether a nucleotide sequence encodes a P-glycoprotein that controls plant growth (page 10, 3rd paragraph of the Remarks). This argument is not found to be persuasive because Applicant does not teach that the function of a P-glycoprotein can be directly correlated to regulation of plant growth, and Applicant has only taught one example in the instant specification.

Applicant's reference to *Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 56 USPQ2d 1332, 1337 (CA FC 2000) is noted. Applicant argues that while the exemplary sequences disclosed are noted, the methods for determining related sequences within the scope of the claims and for determining whether a sequence encodes a P-glycoprotein that functions to control the growth of a plant are known in the art (paragraph spanning pages 10-11 of the Remarks). The Examiner has reviewed *Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 56 USPQ2d 1332 (CA FC 2000), and notes that this decision is directed to the art of making and using nucleotide molecules encoding antibody proteins, an art far more mature than that of P-glycoproteins that

regulate plant growth in the instant case. *In re Wands*, as outlined in a previous Office action, teaches that enablement must be commensurate with the amount of direction or guidance presented, the nature of the invention, the state of the prior art, the relative skill of those in the art, and the predictability or unpredictability of the art. In the instant case, Applicant only teaches a single species of the genus that could regulate plant growth in a transformed plant. The art recognizes that P-glycoproteins are involved in transport of a myriad of substrates through the cell membrane, hence one of skill in the art cannot reasonably predict that a P-glycoprotein, even within the scope of the instant claims, would control plant growth.

Applicant argues that method for transforming a wide variety of plants, including both monocots and dicots, to express a nucleotide molecule of interest are considered routine to those of ordinary skill in the art and would not be considered undue experimentation (paragraph spanning pages 11-12 of the Remarks). This argument is not found to be persuasive because the instant rejection is directed to not only screening through a myriad of transformed plants but also through a myriad of nucleotide molecules as claimed to identify those that modify plant growth in a particular transformed plant. The working example of the claimed method appears prophetic, and it is unclear from the instant specification that the sorghum DW3 gene would have an affect on any plant other than sorghum transformed with said gene.

Claim Rejections - 35 USC § 102

8. Claims 1-6, 9, 11-13, 16, 18, 20, 21 and 24 remain rejected under 35 U.S.C. § 102(b) as anticipated by Sidler *et al* 1998 (The Plant Cell 10:1623-1636). This rejection

is repeated for the reason of record as set forth in the last Office action mailed 4 November 2002. Applicant's arguments filed 4 March 2003 have been fully considered but they are not persuasive.

Applicant argues that the isolated nucleotide molecule disclosed in the Sidler *et al* reference would not hybridize to the nucleotide sequence set forth in either SEQ ID NO: 7 or 8 under the hybridization conditions recited in the amended claims and therefore, the nucleotide molecules encompassed by the amended claims are not anticipated by Sidler *et al* (paragraph spanning pages 15-16 of the Remarks). This argument is not found to be fully persuasive because Applicant provides no evidence that the isolated nucleotide molecule disclosed in the Sidler *et al* reference would not hybridize to the nucleotide sequence set forth in either SEQ ID NO: 7 or 8 under the hybridization conditions recited in the amended claims.

In the instant case, the Examiner does not have sufficient information to determine whether or not the nucleotide molecule disclosed by Sidler *et al* would be encompassed by the instant claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

Claim Rejections - 35 USC § 103

9. Claims 7, 9, 10, 14, 15, 17, 22 and 23 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Sidler *et al* 1998 (The Plant Cell 10:1623-1636), in view of Applicant's admission. This rejection is repeated for the reason of record as set forth in the last Office action mailed 4 November 2002. Applicant's arguments filed 4 March 2003 have been fully considered but they are not persuasive.

Applicant argues that the isolated nucleotide molecule taught in the Sidler *et al* reference would not hybridize to the nucleotide sequence set forth in either SEQ ID NO: 7 or 8 under the hybridization conditions recited in the amended claims and therefore, the nucleotide molecules encompassed by the amended claims are not obvious in view of Sidler *et al* (paragraph spanning pages 16-17 of the Remarks). This argument is not found to be fully persuasive because Applicant provides no evidence that the isolated nucleotide molecule taught in the Sidler *et al* reference would not hybridize to the nucleotide sequence set forth in either SEQ ID NO: 7 or 8 under the hybridization conditions recited in the amended claims.

In the instant case, the Examiner does not have sufficient information to determine whether or not the nucleotide molecule taught by Sidler *et al* would be encompassed by the instant claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

Double Patenting

10. Claims 1-18, 20-24 and 33-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-22 of copending Application No. 10/101,388. This rejection has been modified from that of record as set forth in the last Office action mailed 4 November 2002. Applicant's application 09/711,562 has been abandoned, and application 10/101,388 has been filed as a continuation of 09/711,562. Applicant states on page 18, 2nd paragraph of the response filed 4 March 2003, that upon notification of allowable subject matter in the instant application, Applicants will address this rejection. Applicant's arguments that in view of the abandonment of Application 09/711,562, that the provisional rejection of the

claims under the judicially created doctrine of obviousness-type double patenting should be withdrawn and held until such time that the claims are deemed allowable. This argument is not found to be persuasive because application 10/101,388 has been filed as a continuation of abandoned application 09/711,562, and claims comparable subject matter that renders the claims of the instant invention obvious.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.



David H. Kruse, Ph.D.
15 May 2003

AMY J. NELSON, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600